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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,649	03/01/2004	Franco Vallana	SBC1025USC1	9772
9561	7590	05/20/2005	EXAMINER	
POPOVICH, WILES & O'CONNELL, PA 650 THIRD AVENUE SOUTH SUITE 600 MINNEAPOLIS, MN 55402			GHERBI, SUZETTE JAIME J	
		ART UNIT		PAPER NUMBER
		3738		

DATE MAILED: 05/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/790,649	VALLANA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Suzette J Gherbi	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 01 March 2004.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-31 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-31 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>3/1/04</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-4, 7-19, 22-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dang et al. 6,758,859 in view of von Oepen 6,193,747. Dang et al. discloses the invention as claimed noting figures 4-6 comprising: a stent with a radially expandable tubular body and an active agent for treatment of an implant site, the tubular body having an interior surface and an exterior surface; the tubular body having a plurality of sinusoidal shaped annular elements;, connected to at least one other annular element by a plurality of connection elements; each annular element and each connection element (24) having a rectilinear portion (strut 22) and a curved portion (upper 22 read col. 8, lines 36-41); the exterior surface of the tubular body having a plurality of recesses (30) positioned only in the rectilinear portions, the active agents being contained within the recesses. However Dang et al. does not specify that the connection portion is in the shape of a lambda or the specific percentage ranges of the recesses. Von Oepen teaches the stent structure with lambda shaped connection

elements (noting figure 2b, element 7). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the stent shape i.e. *lambda* connection members because Dang et al. discloses in col. 3, lines 60-63 that the connecting elements may have a variety of shapes and patterns and is deemed a design modification. It is also obvious to one having ordinary skill in the art that the depots (30) of Dang et al. can encompass a variety of percent range coverage (see col. 6, lines 1-3, lines 12-17, lines 56-64, and col. 9, lines 11) in order to custom tailor the amount of therapeutic substance to be released from the stent depending upon which part of the body is to be treated.

3. Claims 5-6, 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dang et al. in view of von Oepen and further in view of Falotico et al. 20010029351. Dang et al. and von Oepen have been disclosed above however they do not specify the rectangular recess. Falotico et al. teaches that rectangular recesses for drug delivery are known in the art noting figure 2 element 106. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the depots of Dang into rectangular shapes because as noted above Dang discloses that a variety of depot configurations are envisioned in order to modify the drug release rate.

***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 14, 29 and 31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,699,281. Although the conflicting claims are not identical, they are not patentably distinct from each other because it is obvious that the claims have the exact language with the exception of minor limitations and it is an obvious broadening in scope of the invention.

#### ***Conclusion***

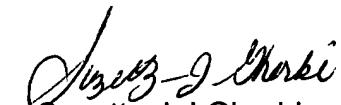
6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ragheb et al. 6,774,278 ; Harish e tal. 6,506,437; Dang et al. 2004/0220662 ; Shanley et al. 2002/0082680 ; Jang 2002/0038145 all show stents with depots for the release of active agents.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 571-272-4751.

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8. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

9. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Suzette J-J Gherbi

13 May 2005